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| APPLICATION NO.                             | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|-----------------|----------------------|---------------------|-----------------|
| 10/073,625                                  | 02/11/2002      | Joseph R. Lakowicz   | UMARYI              | 4325            |
| 23373                                       | 7590 11/29/2006 |                      | EXAMINER            |                 |
| SUGHRUE MION, PLLC                          |                 |                      | TUNG, JOYCE         |                 |
| 2100 PENNSYLVANIA AVENUE, N.W.<br>SUITE 800 |                 |                      | ART UNIT            | PAPER NUMBER    |
| WASHINGTON, DC 20037                        |                 | 1637                 |                     |                 |

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

Paper No(s)/Mail Date \_

6) Other:

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#### **DETAILED ACTION**

- 1. The applicant's response filed 9/8/06 to the Office action has been entered. Claims 28-57, 59, 61-67, 70-82 are pending.
- 2. The finality of the Office action mailed 4/18/06 is withdrawn in light of the new grounds of the rejections.
- 3. Applicant's arguments with respect to claims 28-57, 59, 61-67 and 70-82 have been considered but are most in view of the new ground(s) of rejections.

# Claim Objections

4. Claims 44, and 57 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since the independent claims are drawn to a system which is examined based on the system components and these dependent claims recite further limitations, relating to a method step of "binding", the claimed system is not further limited.

### Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 28, 30-32, 34-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindsay et al. (5,106,729, issued April 21, 1992).

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Lindsay et al. disclose a system comprising a test sample, DNA or RNA and one or more metal particles arranged on a solid support (See column 14, lines 16-26). A glass cell is pushed onto the substrate (See column 7, lines 29-30). The substrate area is 420A by 420A traversed by two molecules (See column 8, lines 6-7)

Since the claims are drawn to a system, the teachings of Lindsay et al. anticipate each component of the system besides the intended use or result of affecting intrinsic emission of electromagnetic radiation of at least one of said one or more biomolecules upon exposing the system to exciting electromagnetic radiation, recited in claim 28, is not given patentable weight.

7. Claims 46-57, 59, 62-67, and 71-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakowicz et al. (WO 99/36779, issued July 22, 1999).

Lakowicz et al. disclose an assay in which a metal-ligand complex is used to bring into interactive proximity with the sample containing the analyte of interest. The mixture is irradiated with electromagnetic light energy to emit the light, which indicates the analyte of interest (See the Abstract and pg. 6, lines 16-24). The metal complexes are platinum metal, (See PG. 11, lines 19-20). The metal complex is a DPPG labeled vesicles (See pg. 12, lines 21-26). The metal-ligand complex is conjugated to human serum albumin (HSA) (See pg. 8, lines 6-8). The distance of the metal complex is 10 to 120 A with the sample (See pg. 6, lines 16-24). Human serum albumin (HSA) is considered as a second biomolecule and is covalently linked to the metal (See column 21, lines 5-15). The ligand is carbon monoxide (See pg. 54, lines 17-21). The complex comprises of mono, bis or tris (heteroleptic) complexes of Ru (ii) and Os(II) and carbon monoxide diimine complexes of Re(I) (See pg. 11, lines 23-26). These teachings suggest that the metal particle is coated with an oxide as recited in claim 49. Lakowicz et al. further disclose that

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the assay is used to quantify the analyte of interest in which a first binding partner and a second binding partner are added to the sample, the first binding partner competes with the analyte to binding to the second binding partner, the first or second binding partner is labeled with a metal-ligand complex and the other is labeled with a photoluminescent energy transfer acceptor wherein the metal-ligand complex and photoluminescent energy transfer acceptor are chosen, when the first binding partner binds to the second binding partner, the metal-ligand complex and the photolumnescent energy transfer acceptor are brought in interactive proximity, producing a detectable change in luminescence (See pg, 53, lines 6-21). The metal-ligand complex typically absorb above 550 nm (See pg. 22, lines 20-22).

Since the claims are drawn to a system or a composition, the teachings of Lakowicz et al. anticipate each component of the system or the composition; the intended use or result of affecting intrinsic emission of electromagnetic radiation of at least one of said one or more biomolecules upon exposing the system to exciting electromagnetic radiation is not given patentable weight.

- 8. (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- 9. Claims 28-33, and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Letsinger et al. (6,602,669, issued August 5, 2003).

Letsinger et al. disclose a system for amplifying a detection signal (See the Abstract). The system comprises a test sample containing a target nucleic acid, which is captured on a substrate (See column 2, lines 52-56). The target molecules are arrayed at discrete positions on a solid surface (See column 2, lines 59-60). Gold nanoparticles coated with oligonucleotides are

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immobilized on a glass substrate or plate by hybridization (See column 2, lines 65-67 and column 3, lines 1-2). The substrate is glass or quartz or plastic and can be any shape or thickness, but generally is flat and thin (See column 6, lines 20-26) recited in claims 46 and 67.

Since the claims are drawn to a system, the teachings of Lindsay et al. anticipate each component of the system; the intended use or result of affecting intrinsic emission of electromagnetic radiation of at least one of said one or more biomolecules upon exposing the system to exciting electromagnetic radiation, recited in claim 28, is not given patentable weight.

## Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 61 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lakowicz et al. (WO 99/36779, issued July 22, 1999) as applied to claims 46-57, 59, 62-67, and 71-82 in view of Lindsay et al. (5,106,729, issued April 21, 1992).

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The teachings of Lakowicz are set forth in section 7 above. Lakowicz does not disclose that the metal particle is silver.

Lindsay et al. disclose a method of determining the nucleic acid sequence in which the metal particle is silver (See column 14, lines 33-37).

One of ordinary skill in the art would have been motivated to apply the silver metal as a metal particle as taught by Lindsay et al. in the method of Lakowicz et al. because by doing so, the method of Lindsay et al. provides remarkably and unexpected enhanced contrast (See column 2, lines 56-57). It would have been <u>prima facie</u> obvious to apply the metal particle, which is silver in the system or the composition as claimed.

# Summary

- 12. No claims are allowable.
- 13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung November 16, 2006

> KENNETH R. HORLICK, PH.D PRIMARY EXAMINED

> > 11/27/06